K091006

FEB 2 5 2010

510(k) SUMMARY
Arstasis, Inc.
ITG Vascular Access System
510(k) Notification _____

GENERAL INFORMATION

Manufacturer: Arstasis, Inc.
1021 Howard Avenue, Suite C
San Carlos, CA 94070
Phone: (650) 508-1549
Facsimile: (650) 594-4326
Establishment Registration Number: Pending

Contact Person: Dominique Filloux
Vice President Research & Development, Clinical and Regulatory Affairs

Date Prepared: February 24, 2010

DEVICE INFORMATION

Trade name: ITG Vascular Access System

Classification Names: Catheter, Introducer §870.1340 (DYB)

Classification: Class II

PREDICATE DEVICES

Cardiva Medical, Inc. Vasostasis / Boomerang System (K041486 / K061075)
Boston Scientific Super Sheath Introducer Sheath (K060190)
Merit Medical Prelude Introducer Sheath / Kit (K071059)

INTENDED USE/INDICATIONS FOR USE

The Arstasis ITG Vascular Access System is intended to provide access for the percutaneous introduction of devices into the peripheral vasculature and to promote hemostasis at the arteriotomy site as an adjunct to manual compression. The ITG Vascular Access System is indicated for use in patients undergoing diagnostic femoral artery catheterization procedures using 5F or 6F introducer sheaths.

DEVICE DESCRIPTION

The ITG Vascular Access System is a sterile, single use system that consists of the following components: ITG Vascular Access Device, ITG Guide Wire (0.016" x 80 cm) and ITG Introducer Needle (21 gauge). The ITG Vascular Access System is designed to be used with the Merit Medical Prelude 5F or 6F Sheath Introducer (Merit Catalog Number PSI-6F-11-018 and PSI-5F-11-018; 510(k) K050962, K070159 and K073035; CE Mark CE_{0123}). The ITG Vascular Access Device with integrated needle is designed to traverse the femoral artery wall at a shallow, oblique angle as it enters the arterial lumen. The ITG Vascular Access System is used at the beginning of the procedure and creates a shallow vascular access pathway that, in conjunction with manual compression, helps reduce hemostasis time as compared to manual compression alone after removal of the procedural introducer sheath.

The ITG Vascular Access Device is a sterile, single use device and is comprised of four primary components: (1) guide cannula, (2) anchor mechanism, (3) shaft, and (4) handle with control features.

The guide cannula consists of a polymeric, single concentric lumen catheter that extends from the distal tip of the guide cannula to the anchor mechanism and has an access port that is compatible with a 0.016" Guide Wire. An anchor mechanism is located between the guide cannula and the catheter shaft. The anchor mechanism is used to position the device relative to the vessel wall prior to advancement of the integrated needle, and is also used during guide wire placement. The catheter shaft extends from the anchor mechanism proximally to the distal end of the device handle. At the distal end of the shaft there is a flexible, deflectable section that is controlled by a lever on the device handle. The integrated needle is housed at the distal end of the deflectable section and is attached to the plunger on the handle.

The handle contains controls that operate the different features of the ITG Vascular Access Device. The plunger at the proximal end of the handle controls deployment of the heel and integrated needle. The handle lever articulates the flexible, deflectable section of the shaft from a "path formation position" to a "deflected position" in order to control the path of the integrated needle. The lever is pressed against the handle to deflect the flexible section of the device in order to redirect the needle into the vessel lumen. Pressing the lever also releases the internal stop mechanism to allow full deployment of the integrated needle. Full deployment of the integrated needle into the vessel lumen is accomplished by completely depressing the plunger.

The 0.016" Guide Wire is inserted into the plunger port and advanced through the ITG Vascular Access Device into the arterial lumen. Plunger retraction automatically releases the anchor heel and retracts the integrated needle for device removal. The 0.016" Guide Wire remains in the arterial lumen as the ITG Vascular Access Device is removed. An introducer sheath is advanced over the 0.016" Guide Wire and the user proceeds with the percutaneous procedure.

DATA DEMONSTRATING SUBSTANTIAL EQUIVALENCE

Test data provided in the subject Premarket Notification include: a) bench performance b) biocompatibility c) preliminary animal (in non GLP studies) and cadaver assessments[1], and d) the results of clinical investigations for the ITG Vascular Access System. Bench performance testing of the ITG Vascular Access System demonstrates that the ITG System meets or exceeds the performance requirements for the intended clinical use of the system. Biocompatibility testing of ITG Vascular Access System was conducted pursuant to FDA's Guidance Document (#G95-1), Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing (1995)". Based on the test results, the ITG Vascular Access System is biocompatible.

Multiple clinical evaluations of the ITG Vascular Access System were conducted. The short term safety and clinical performance of ITG Vascular Access System were established. The long term safety, as well as the ability to access and re-access, was retrospectively studied in a smaller cohort of patients. In summary, the cumulative clinical results demonstrate that the ITG Vascular Access System is substantially equivalent to its predicates in providing access to the arterial lumen and facilitating the introduction and placement of devices into the peripheral vasculature and achievement of hemostasis.

[1] The Preliminary Animal Studies and Cadaver Assessments were conducted using prototypes of a similar design and configuration.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Arstasis, Inc.
c/o Mr. Dominique Filloux
Vice President, Research and Development and RA/CA
1021 Howard Avenue, Suite C
San Carlos, CA 94070

Re: K091006
Arstasis ITG Vascular Access System
Regulation Number: 21 CFR §870.4450
Regulation Name: Catheter, Introducer
Regulatory Class: Class II (Two)
Product Code: DYB
Dated: December 30, 2009
Received: December 31, 2009

Dear Mr. Filloux:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K091006

Device Name:

ITG Vascular Access System

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Prescription Use ✓ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

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